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(54) Electrode system for a defibrillator.

(57) An electrode system for a defibrillator with an electrode (22) placeable in peripheral cardiac veins.

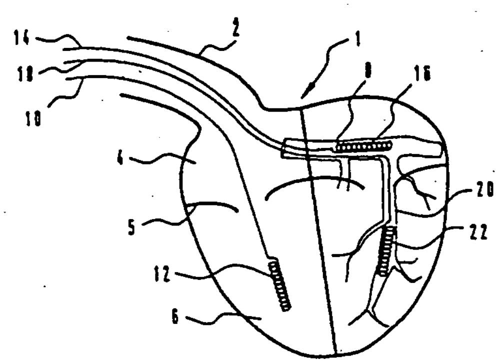

FIG 1

EP 0 601 340 A1

This invention relates generally to an electrode system intended for proximal connection to a cardioverter/defibrillator and for distal placement in the heart region in order to deliver electrical energy to the heart from the cardioverter/defibrillator to terminate an arrhythmia in the heart. More specifically, the invention relates to a system with at least two electrodes as set forth in the beginning of patent claim 1.

In defibrillation/cardioversion (cardioversion in this context refers to lower energy defibrillation; the collective designation defibrillation will be used hereinafter) with the aid of e.g. a three-electrode system with two intravascular electrodes, one of these intravascular electrodes is normally placed in the right ventricle and another in either the superior vena cava or, less commonly, the inferior vena cava or, possibly, the coronary sinus and its tributary along the base of the heart. In order to achieve high utilization of the energy stored in the defibrillator and good distribution of current in the heart, while simultaneously obviating the need for major surgery (thoracostomy), the third electrode is devised as a subcutaneous, large-area electrode, i.e. a patch electrode. The patch electrode is usually placed in the vicinity of the left ventricle, between the patient's ribs and skin.

Electrode systems with the described placements are shown, among others, in US-A-4,708,145. In addition to the intravascular electrodes shown there with a common electrode cable for a plurality of electrodes in the right ventricle and superior vena cava, separate electrode cables for different electrodes and a separate sensor electrode to detect cardiac events are also possible. This is shown in US-A-4,727,877, EP-A-O 373 953 and US-A-5,044,375 respectively. The use of systems with only two (non-epicardiac) electrodes is also known. One example of this is shown in US-A-3,942,536, in which the electrodes, located along the same electrode cable, are placed in the superior vena cava and right ventricle respectively.

When the heart's coronary vessels on the venous side are put to use as the site of at least one of the defibrillation electrodes in prior art systems, the vessels used have been the coronary sinus and its tributary, the great cardiac vein, along the base of the heart or, to put it another way, along the heart's valve plane.

The present invention is based on the inventors' understanding that the venous side of the coronary vessels running between the base and apex of the heart, generally referred to as the heart's peripheral veins, such as the great, middle and small cardiac veins, offers opportunities for placing at least one defibrillation electrode, this electrode, interacting with the other electrodes in the system, having been shown to produce high utilization of the energy stored in the defibrillator and favorable distribution of current in the heart. In view of the described prior art, the favorable effect of this placement is surprising, since e.g. the above-mentioned EP-A 0 373 953 emphasizes the importance of restricting electrode placement to coronary vessels along the base of the heart (col. 6, lines 24-33).

The object of the invention is to achieve an electrode system in which at least one electrode is sited in a coronary vessel and in which high utilization of the energy stored in the defibrillator is combined with a favorable distribution of current in the heart.

This object is achieved with an electrode system of the above-described kind with the features specified in patent claim 1.

According to the invention, an electrode system is thereby attained in which the electrodes are devised for intravenous placement in the heart's peripheral veins.

The embodiments described in sub-claims according to the invention show advantageous electrode configurations, whereby at least some of the venous electrodes can be arranged along a common electrode cable and/or be equipped with means for affixing them to the inner venous wall. The fixation means can have the shape of a hollow, resilient cylinder which achieves fixation by means of radial expansion. The hollow cylindrical shape of the electrode enables blood to flow unimpeded through the electrode. Other advantageous embodiments are noted in the sub-claims.

The electrode system according to the invention is presented below in greater detail, referring to an attached drawing in which

FIG. 1 schematically depicts a heart in cross-section (frontal plane) with the electrode system connected to the heart according to a first embodiment of the invention;

FIGS. 2-8 schematically depict a heart in cross-section (frontal plane) with the electrode system connected to the heart according to other embodiments of the invention.

Identical reference designations designate identical or similar parts in all the FIGURES.

FIG. 1 shows a cross-section of a heart 1 and a plurality of blood vessels important to the invention. A first electrode cable 10, introduced via the superior vena cava 2, passes through the right atrium 4 and valve plane 5 and exits into the right ventricle 6. At or near its distal end, the cable 10 is provided with an electrode 12 which can be anchored in the right ventricle. A second electrode cable 14, also introduced via the superior vena cava 2, passes through the right atrium 4 but, in contrast to the cable 10, in such a way that it exits into the coronary sinus 8 or its tributary along the base of

the heart 1. At its distal end, the cable 14 is provided with an electrode 16 which can be anchored in the coronary sinus or its tributary. A third electrode cable 18, also introduced via the superior vena cava 2, passes through the right atrium 4 and coronary sinus 8 and possibly its tributary so the cable exits into a peripheral vein 20, shown in FIG. 1, of the heart 1. At its distal end, the cable 18 is provided with an electrode 22 which can be anchored in the peripheral vein 20. The electrodes 12, 16, 22 are connectable to the defibrillator (not shown) via existing electrical conductors in the respective cables 10, 14, 18.

The electrode system according to FIG. 2 differs from the system shown in FIG. 1 because the electrode 12 placed in the right ventricle 6 has been replaced with the electrode 26, placed in the inferior vena cava 7, which is connectable to the defibrillator via an existing conductor in the electrode cable 24.

The electrode system according to FIGS. 3 and 4 differs from the system in FIG. 1 because the electrode 12 placed in the right ventricle 6 is replaced by the electrode 30 (FIG. 3) placed in the superior vena cava 2 or with a subcutaneous patch electrode 17 (FIG. 4) placed near the right ventricle 6. The electrodes 30 and 17 are connectable to the defibrillator via existing conductors in the electrode cable 28 and 19 respectively. "Subcutaneous" placement here refers to placement between the ribs and skin. The defibrillator's enclosure can alternately be used as a patch electrode.

The electrode system according to FIGS. 5, 6, 7 and 8 show additional advantageous configurations of described electrode elements. The electrode system according to FIGS. 5, 6, 8 can thereby be regarded as a system in which the electrode 28 in the inferior vena cava 2 replaces the electrode 16 in the coronary sinus 8 in the system according to FIGS. 1, 2, 4 respectively. In FIG. 7, it should be noted that the peripheral vein 20 shown, as in other configurations, is an example of a plurality of peripheral cardiac veins which could be employed as sites for the electrode 22, the choice of peripheral vein being governed by e.g. the placement of other electrodes.

Connection of the electrodes according to FIGS. 1-8 to the defibrillator and to one another can be achieved in different ways. For example, the electrodes 16, 22 shown in FIG. 1 can be inter-connected in such a way that the defibrillation pulse passes between these electrodes, on the one hand, and the electrode 12 in the right ventricle 6, on the other hand.

However, the electrodes 12, 16, 22 can be inter-connected so the defibrillation pulse passes between one of these electrodes, on the one hand, and the other two electrodes, on the other hand. Alternately, each of the electrodes 12, 16, 22 can be given a different voltage in defibrillation or, as an additional alternative, emit defibrillation pulses sequentially in pairs. Monophasic, biphasic or multiphasic defibrillation pulses can be used.

Moreover, the cables 14, 18 for the two electrodes 16, 22 shown in FIG. 1, can be replaced with a common electrode cable for both the electrodes 16, 22. The inferior vena cava 6 can be used as an alternative to the described routing of intravascular electrodes through the superior vena cava 2. The intravascular electrodes introduced via the former route can also share an electrode cable or have separate electrode cables. In the configuration shown in FIG. 3, the electrodes 16, 22 30 can have e.g. a single, common catheter.

All configurations, with the exception of the subcutaneous patch electrode 17, using the same implantation route for a plurality of electrodes, could also obviously be arranged on a common electrode cable.

The described electrode configurations can also be supplemented with a separate sensor electrode for detecting cardiac events and/or a sensor for sensing different parameters related to e.g. cardiac hemodynamics. The sensor electrode's electrode cable could also include a stimulation electrode for a pacing function.

The intravascular electrodes 16, 22, 26, 30 are kept in place in the respective vein by a construction making them radially expandable, forming in the expanded position at least the contours of a hollow cylinder. Defibrillation electrodes of this type are described in detail in the applicants' simultaneously filed patent application entitled "Defibrillation Electrode", their reference GR 92 P 7364, this document serving as a part of the present application so as to avoid repetition here. Thus, the intravascular electrodes 16, 22, 26, 30 are kept in place in the respective vein by being devised as helices whose bias tension, transverse to the longitudinal axis of the helix, exerts pressure on the venous wall. To avoid repetition, only helical fixation of the electrode 26 in the inferior vena cava 7 will be described below, but the description obviously covers the other intravascular electrodes. In its pre-shaped state, the helical electrode 26 can be envisaged as being helically wound around an imaginary cylinder whose external diameter is somewhat larger that the inner diameter of the inferior vena cava 7. The helix can be made of an electrically conductive, biocompatible material. The electrode 26 is connected to the electrode cable 24 in such a way that they jointly form a continuous unit. A centrally located longitudinal channel, into which a stylet can be introduced, runs through the electrode 26 and the electrode cable 24. During implantation, the electrode 26 is straightened out

with the aid of the stylet. The electrode 26, whose diameter at implantation is therefore smaller than the diameter of the blood vessels it is to traverse, can then be introduced into the inferior vena cava 7. When the implanting physician reaches an appropriate site for the electrode 26 in the inferior vena cava 7, the stylet is withdrawn, and the electrode 26 then reassumes its pre-shaped, helical configuration. The pressure of the helix against the venous wall keeps the helix at the desired site. In the affixed position, the electrode 36 forms a relatively large electrode surface against the vascular wall. At the same time, the helical electrode 26 has the advantage of allowing blood in the vessel to flow unimpeded through the interior of the helix. The risk of clot formation is thereby minimized. In addition, the electrode 26 can be easily re-positioned if the stylet, re-inserted into the central channel, is used to straighten out the electrode 26. Thus, the implanted physician can readily find a site for the electrode 26 which, with the other electrodes, provides favorable distribution of current in heart tissue.

In implantation, the physician can use an introductory catheter instead of a stylet. The electrode cable 24 with the straightened electrode 26 is inserted in the introductory catheter, the latter being sufficiently stiff to keep the electrode 26 straightened out during implantation. When the electrode 26 has been advanced to the desired position in the inferior vena cava 7, the introductory catheter can be withdrawn so the electrode reassumes its precoiled configuration.

In instances in which the electrodes, e.g. electrodes 16, 22, are arranged on a common electrode cable, implantation can be performed with the aid of a single stylet running through a central channel through all the electrodes and the electrode cable. Both electrodes are then straightened out after implantation. When the electrode 22 reaches the desired position, the stylet is withdrawn just enough to allow the electrode 22 to reassume its helical configuration, the electrode 16 thereafter being positioned at the desired site in the coronary sinus 8. When the electrode 16 has been properly positioned, the stylet is withdrawn completely so the electrode 16 reassumes its preshaped configuration. An introductory catheter could also be used here instead of a stylet.

The electrode 16 intended for placement in the coronary sinus 8 and its tributary along the base of the heart could consist of e.g. two sub-electrodes placed in the coronary sinus 8 and its tributary respectively. The two sub-electrodes can be arranged on a common extension of e.g. the electrode cable 14. The two sub-electrodes are placed in the coronary sinus 8 and its tributary so individually adapted, additionally improved distribution of current in the heart is attained. Implantation here is carried out in the above-described way. More than two sub-electrodes could be used. A system employing sub-electrodes could also be employed for the electrode 22 placeable in a peripheral vein 20.

REFERENCE DESIGNATIONS

1
Heart
2
Superior vena cava
4
Right atrium
5
Valve
6
Right ventricle
7
Inferior vena cava
8
Coronary sinus and its tributary
20
Peripheral vein
10, 14, 18, 24, 19, 28
Electrode cable
12, 16, 22, 26, 30
Electrodes
17
Patch electrode

Claims

1. An electrode system for a defibrillator with at least two electrodes, wherein the first of the at least two electrodes are devised for intravenous placement in one of the heart's peripheral veins (20).

2. An electrode system of claim 1, wherein a second of the at least two electrodes is devised for intravenous placement in the coronary sinus (8) and its tributary along the base of the heart (FIGS. 1, 2, 3, 4).

3. An electrode system of claim 2, wherein the system comprises a third electrode.

4. An electrode system of claim 3, wherein the third electrode (12) is devised for placement in the right ventricle (6) (FIG. 1).

5. An electrode system of claim 3, wherein the third electrode (26) is devised for intravenous placement in the inferior vena cava (7) (FIG. 2).

6. An electrode system of claim 3, wherein the third electrode (30) is devised for intravenous placement in the superior vena cava (2) (FIG. 3).

7. An electrode system of claim 3, wherein the third electrode consists of a subcutaneous patch electrode (17) placeable in the vicinity of the right ventricle (6) (FIG. 4).

8. An electrode system of claim 1, wherein the second (30) of the at least two electrodes is devised for intravenous placement in the superior vena cava (2) (FIGS. 5, 6, 8).

9. An electrode system of claim 8, wherein the system comprises a third electrode.

10. An electrode system of claim 9, wherein the third electrode (12) is devised for placement in the right ventricle (6) (FIG. 5).

11. An electrode system of claim 9, wherein the third electrode (26) is devised for intravenous placement in the inferior vena cava (7) (FIG. 6).

12. An electrode system of claim 9, wherein the third electrode consists of a subcutaneous patch electrode (17) devised for placement in the vicinity of the right ventricle (6) (FIG. 8).

13. An electrode system of claim 1, wherein a second (12) and a third (26) of the at least two electrodes are devised for placement in the right ventricle (6) and for intravenous placement in the inferior vena cava (7) respectively (FIG. 7).

14. An electrode system of any of the preceding claims, wherein at least two of the intravenously placeable electrodes are separately arranged on the same electrode cable.

15. An electrode system of any of the preceding claims, wherein the intravenous electrodes in the electrode system have means for affixing the electrodes to the inner wall of the vein in which they are located.

16. An electrode system of claim 15, wherein the means for fixation is achieved when the electrode in the affixed position has a hollow, cylindrical shape whose radius exceeds the radius of the vein enough to affix the electrode by pressure to the inner wall of the vein.

17. An electrode system of claim 16, wherein the electrode consists of a helix whose helical turns comprise at least a part of the cylinder's mantle.

18. An electrode system of either of claims 7 or 12, wherein the patch electrode can consist of at least a part of the defibrillator enclosure.

19. An electrode system of any of the preceding claims, wherein the electrode intended for placement in the coronary sinus and its tributary along the base of the heart or in a peripheral cardiac vein consists of at least two separate sub-electrodes, the most distal of the at least two sub-electrodes connected to the proximal sub-electrode by a common electrode cable.

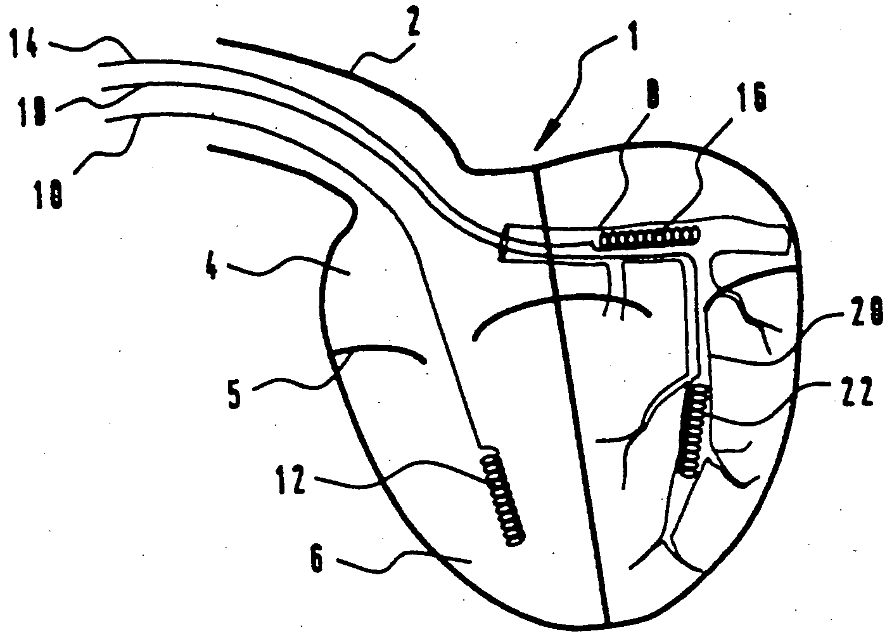

FIG 1

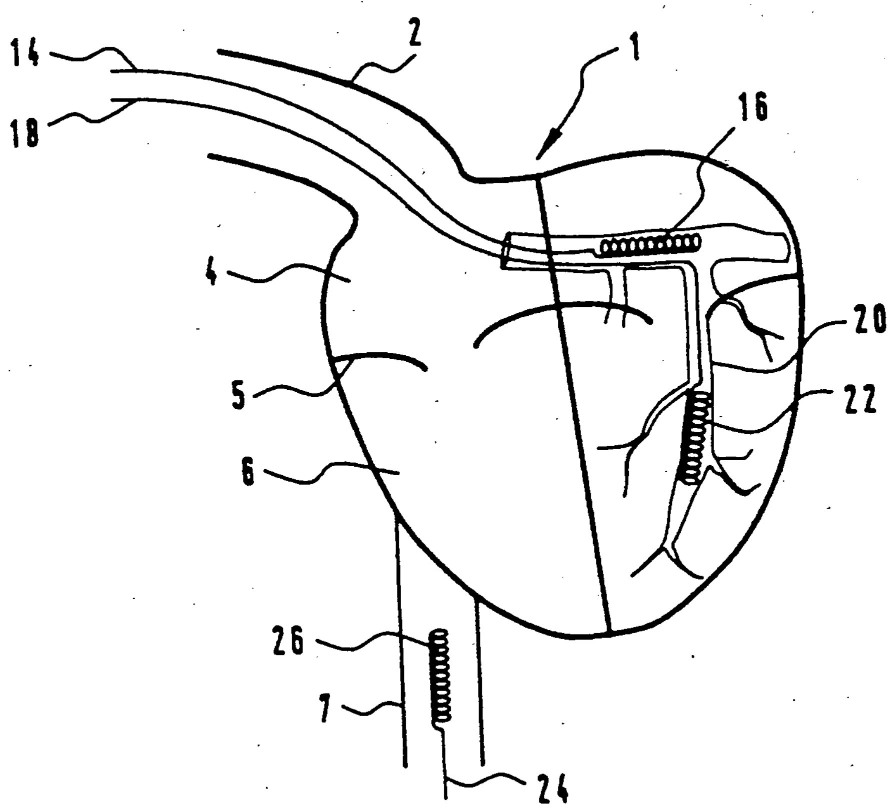

FIG 2

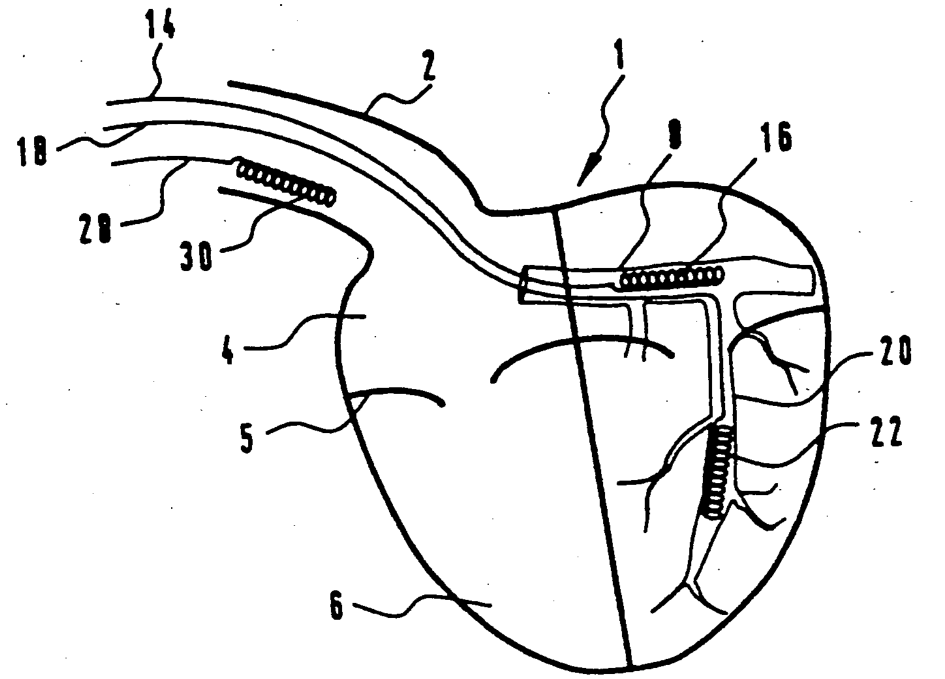

FIG 3

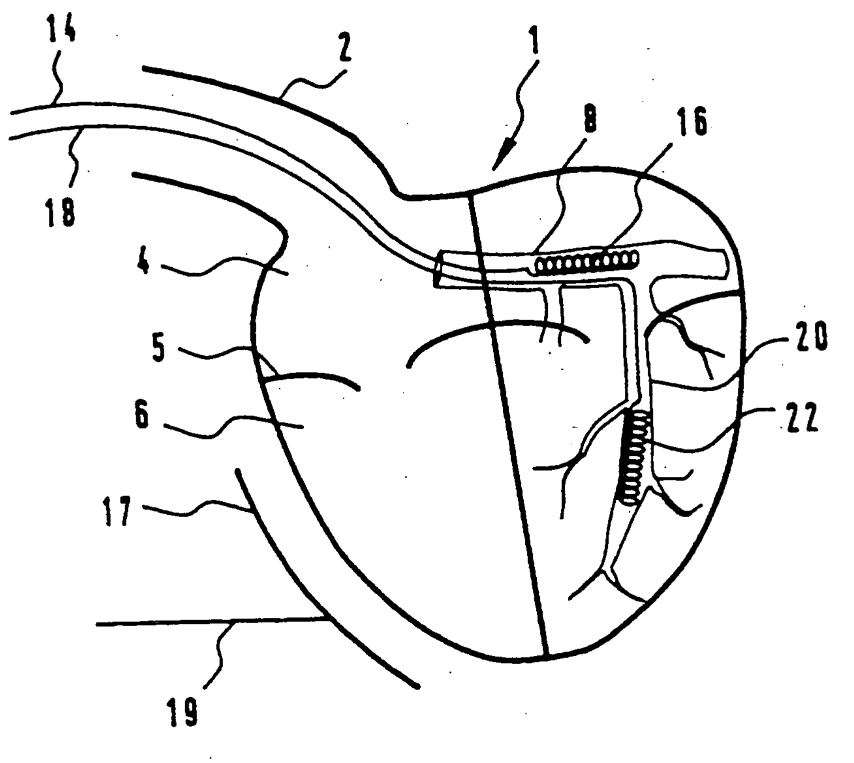

FIG 4

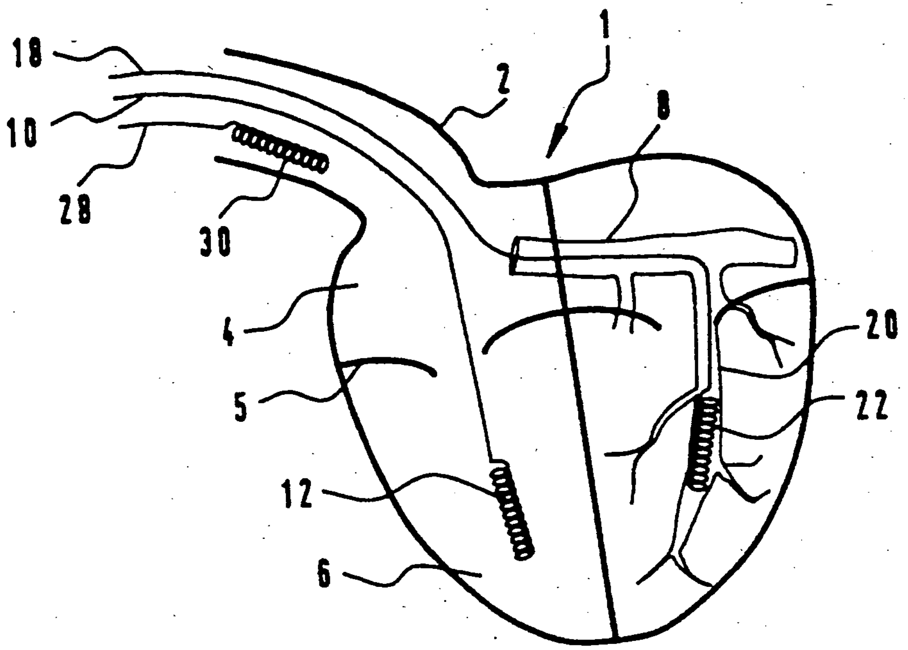

FIG 5

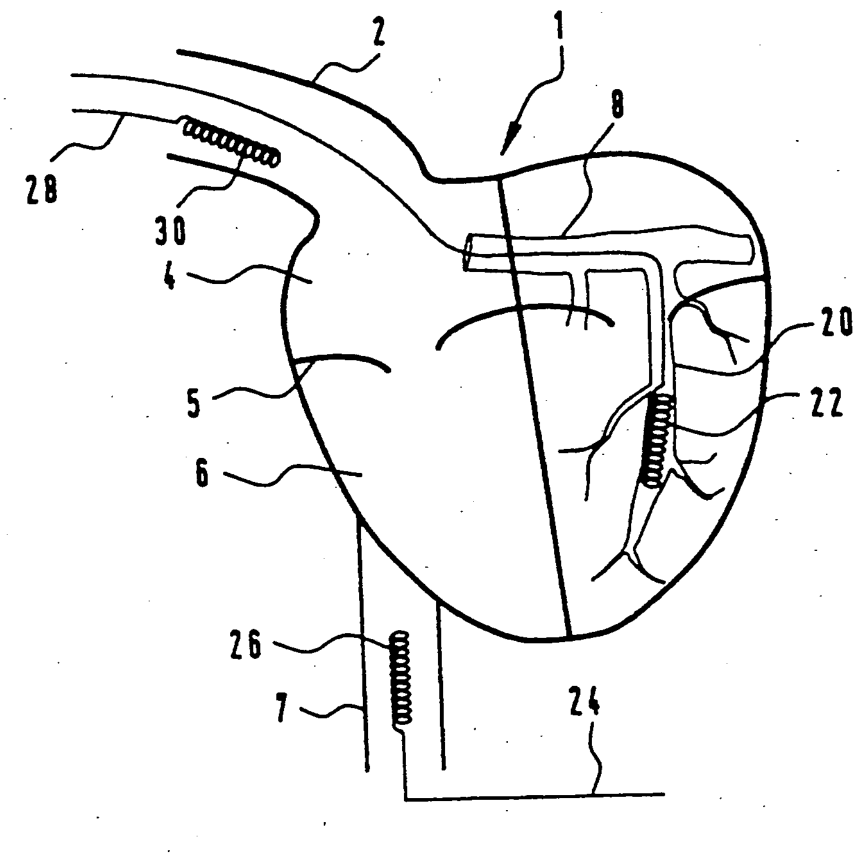

FIG 6

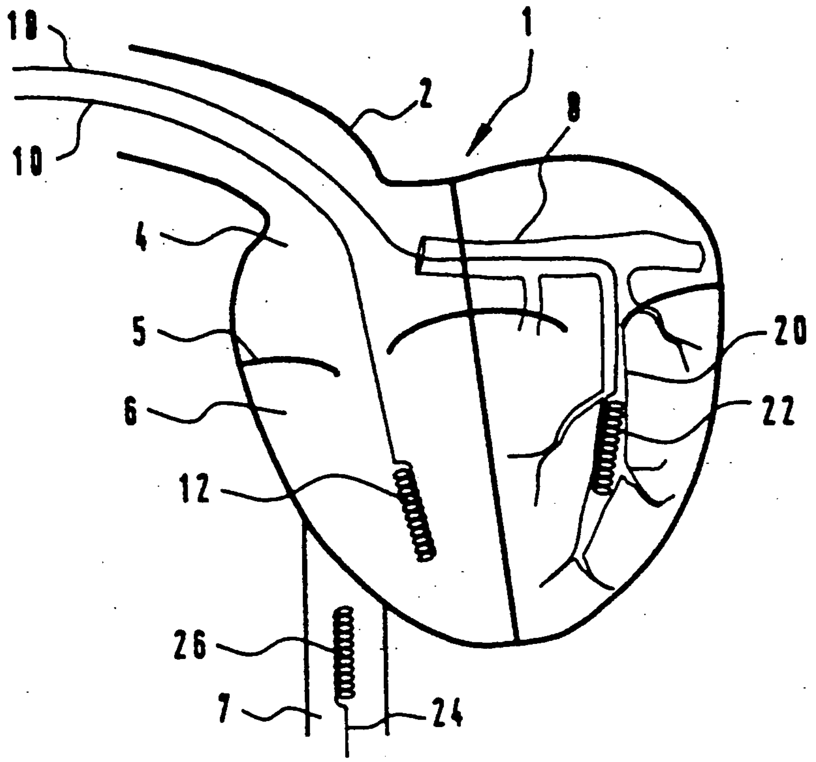

FIG 7

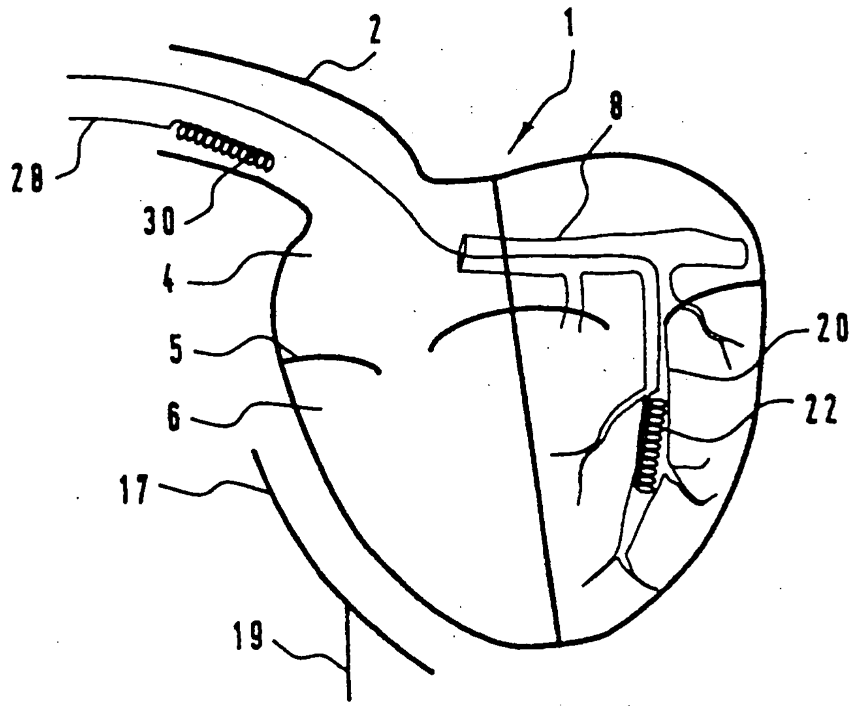

FIG 8

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DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
X	WO, A2, 9218198 (INCONTROL INC), 29 October 1992 (29.10.92) * page 31, line 34 - page 32, line 4; page 42, line 18 - page 43, line 6, figures 9,14 *	1-4	A61N 1/05 A61N 1/39
Y		6-10, 12, 14-17	
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A		1-4	
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Y	WO, A1, 9211898 (MEDTRONIC INC), 23 July 1992 (23.07.92) * page 2, line 24 - page 4, line 4; page 6, line 32 - line 35, figures 1-4, abstract *	15-17	
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The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
STOCKHOLM	7 March 1994	BENGTSSON RUNE

CATEGORY OF CITED DOCUMENTS

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DOCUMENTS CONSIDERED TO BE RELEVANT			
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A	US, A, 5163427 (JOHN G. KEIMEL), 17 November 1992 (17.11.92) * column 3, line 32 - line 48, figure 1, abstract * -----	1-4	
			TECHNICAL FIELDS SEARCHED (Int. Cl.5)
			A61N

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